

**Congress of the United States**  
**Washington, DC 20515**

May 23, 2005

Ms. Dara Corrigan  
Acting Principal Deputy Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Room 5250, The Cohen Building  
330 Independence Avenue, S.W.  
Washington, DC 20201

Dear Ms. Corrigan:

We are very concerned about recent reports that in 2004, the Food and Drug Administration (FDA) requested a "minority opinion" by dissenting panelist and evangelical conservative Dr. W. David Hager, during its consideration of Barr Laboratories' application to allow over-the-counter sales of emergency contraception (EC). According to reports, this "minority opinion" was requested by the FDA to outline a rationale for why over-the-counter sales of EC should be rejected, and came shortly after the FDA's Advisory Panel voted overwhelmingly in favor (23-4) of over-the-counter sales of Barr Laboratories' Plan B emergency contraceptive. We, therefore, request an investigation into whether this atypical "minority opinion" unduly influenced FDA's decision in May 2004 to reject Barr Laboratories' application.

We are deeply disturbed by reports that FDA disregarded the recommendation of its expert Advisory Panel and instead may have used the opinion of just one of the dissenting panelists to justify a politically motivated decision to deny women access to EC. As the FDA's Advisory Panel concluded, emergency contraception meets standard criteria for over-the-counter use: low toxicity, no potential for overdose or addiction, no teratogenicity (is not harmful to an existing pregnancy), no need for medical screening, self-identification of the need, uniform dosage and no important drug interactions.

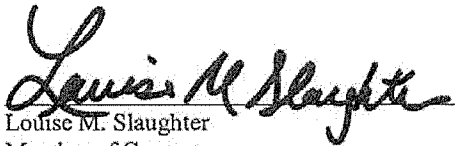
To make such an important decision based on politics instead of science has serious implications for the health of women across the country. The Alan Guttmacher Institute estimates that increased use of EC accounted for up to 43 percent of the total decline in abortion rates between 1994 and 2000. In addition, EC is often the only contraceptive option for the 300,000 women who are raped each year. Unfortunately, many women do not know about EC and many face insurmountable barriers in accessing this important product. A recent study in the *Annals of Emergency Medicine* found that less than 17 percent of hospitals dispense emergency contraception at the woman's request, without restrictions. Yet, scientific data suggest that increased timely access to EC could significantly reduce our nation's still staggering rates of unintended pregnancy and decrease the number of abortions performed in our nation by hundreds of thousands.

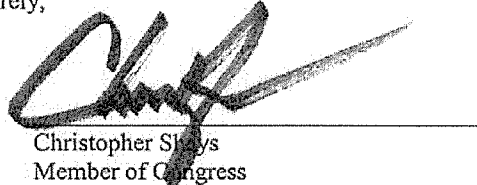
The recent reports about Dr. Hager raise serious concerns that science and safety have taken the back seat to politics in the FDA's decision not to permit over-the-counter sales of EC. The

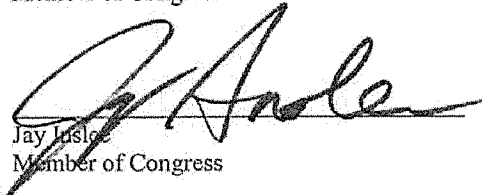
scientific facts irrefutably show that EC is a safe, effective way for women to prevent unintended pregnancy. We, therefore, urge you conduct a thorough investigation into reports that the FDA requested a "minority opinion," and determine if sound scientific methodologies were employed when this decision was made to overrule the FDA's advisory panel.

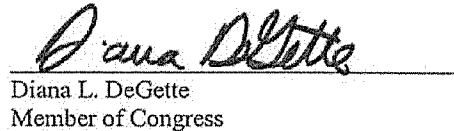
Thank you for your attention to this important matter. We look forward to your response.

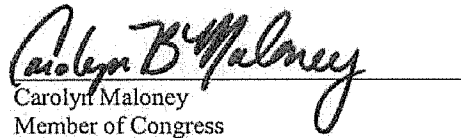
Sincerely,

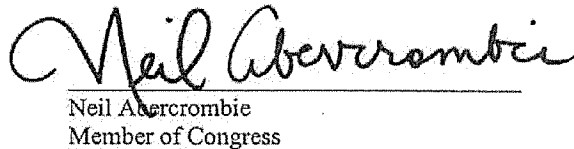
  
Louise M. Slaughter  
Member of Congress

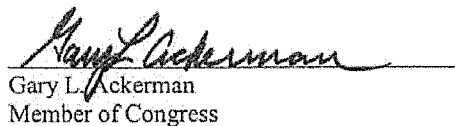
  
Christopher Shays  
Member of Congress

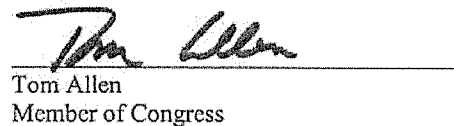
  
Jay Inslee  
Member of Congress

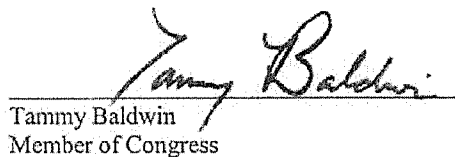
  
Diana L. DeGette  
Member of Congress

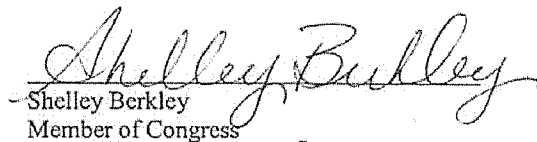
  
Carolyn B. Maloney  
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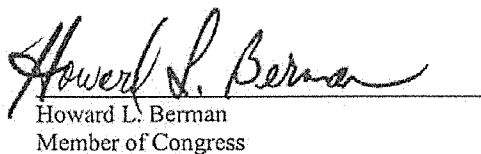
  
Neil Abercrombie  
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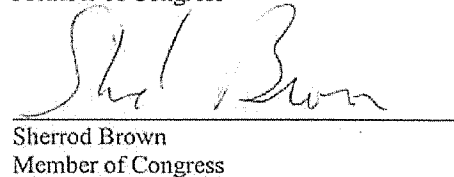
  
Gary L. Ackerman  
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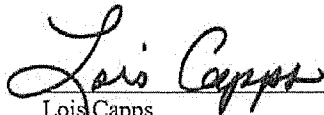
  
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Tammy Baldwin  
Member of Congress

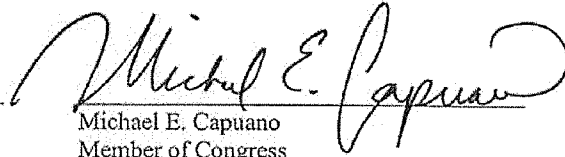
  
Shelley Berkley  
Member of Congress

  
Howard L. Berman  
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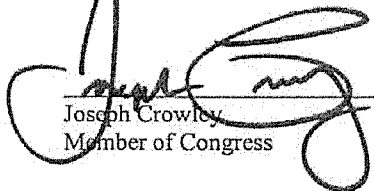
  
Sherrod Brown  
Member of Congress



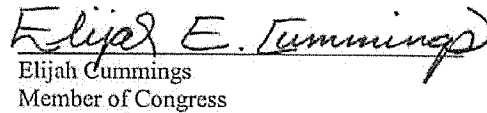
Lois Capps  
Member of Congress



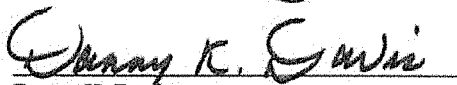
Michael E. Capuano  
Member of Congress



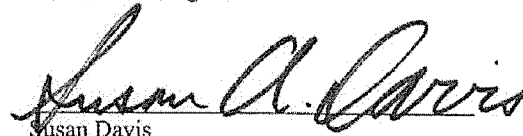
Joseph Crowley  
Member of Congress



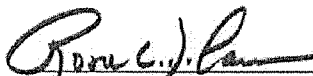
Elijah Cummings  
Member of Congress



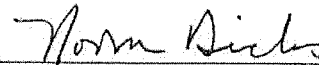
Danny K. Davis  
Member of Congress



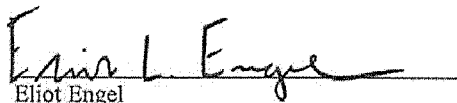
Susan Davis  
Member of Congress



Rosa DeLauro  
Member of Congress



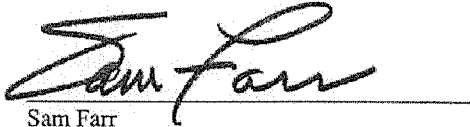
Norm Dicks  
Member of Congress



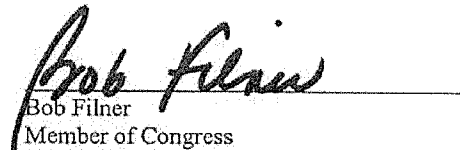
Eliot Engel  
Member of Congress



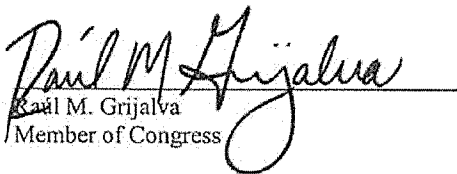
Lane Evans  
Member of Congress



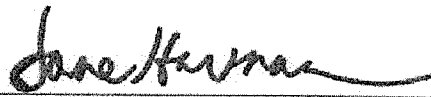
Sam Farr  
Member of Congress



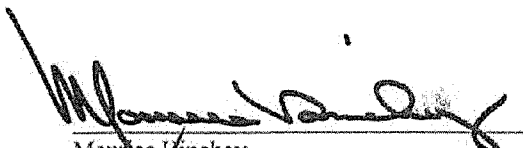
Bob Filner  
Member of Congress





Raúl M. Grijalva  
Member of Congress

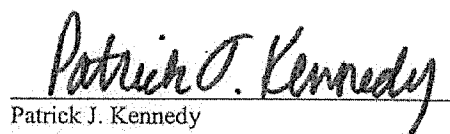


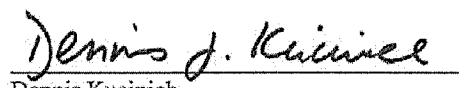
Jane Harman  
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Maurice Hinchey  
Member of Congress

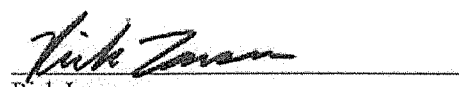
  
Rush Holt  
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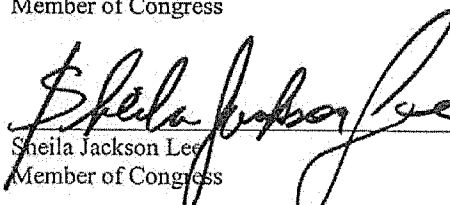
  
Steve Israel  
Member of Congress

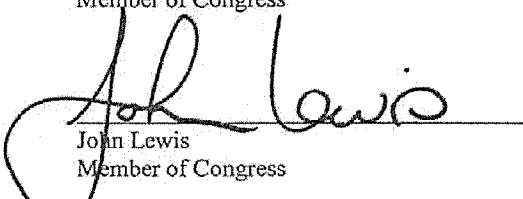
  
Patrick J. Kennedy  
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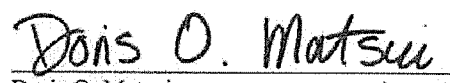
  
Dennis Kucinich  
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Tom Lantos  
Member of Congress

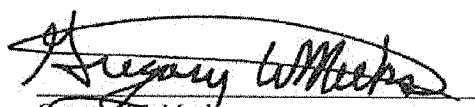
  
Rick Larsen  
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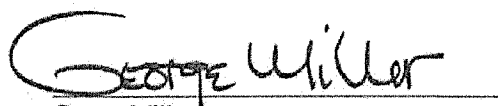
  
Sheila Jackson Lee  
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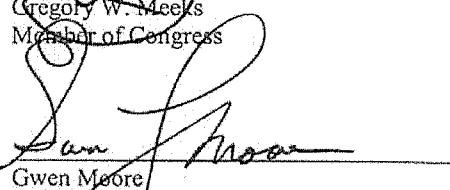
  
John Lewis  
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Doris O. Matsui  
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James P. McGovern  
Member of Congress

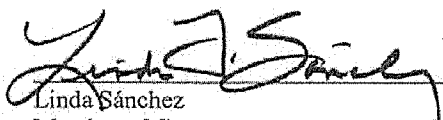
  
Gregory W. Meeks  
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George Miller  
Member of Congress

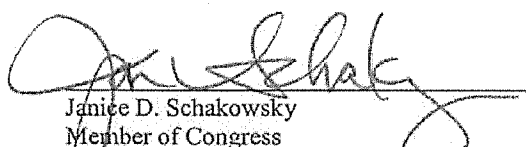
  
Gwen Moore  
Member of Congress


  
Jim Moran  
Member of Congress

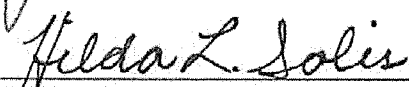
  
John W. Olver  
Member of Congress

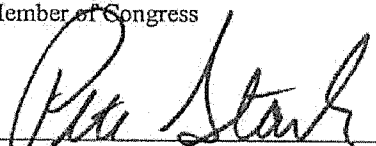
  
Linda Sánchez  
Member of Congress

  
Bernard Sanders  
Member of Congress


  
Janice D. Schakowsky  
Member of Congress

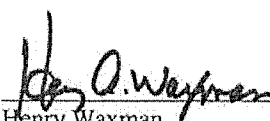
  
Debbie Wasserman Schultz  
Member of Congress

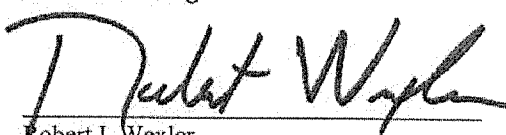
  
Hilda L. Solis  
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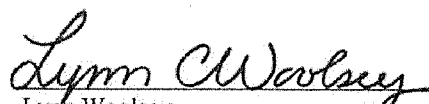
  
Pete Stark  
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Diane E. Watson  
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